

REMARKS

Claims 1-10 are pending in the present application. Claims 1 and 3 have been amended.

The amendments to the claims are solely to advance prosecution. Applicants, by amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert the original claim scope of any claim amended herein, in a continuing application.

Claim 1 has been amended to recite a "warming patch, comprising: a support; and an adhesive layer disposed on at least one surface of said support, the adhesive layer comprising a warming material, l-menthol, and polyethylene glycol as a residual irritation reducing agent, and the amount of said l-menthol and said polyethylene glycol are respectively 0.5-1.5 mass% and 3-25 mass%, based on the total amount of said adhesive layer." Support for this amendment can be found, for example, in claim 3 as originally filed.

Claim 3 has been amended to correct a minor typographical error. In particular, a comma has been deleted from claim 3.

No new matter has been added.

In view of the following, further and favorable consideration is respectfully requested.

I. At page 3 of the Official Action, claims 1-3 have been rejected under 35 USC § 103(a) as being obvious over lida (JP 1991-161435).

The Examiner asserts that lida teaches the components of 0.2% capsicum extract, 0.5-1.0% 1-menthol and 1.0-10% polyethylene oxide. Additionally, the Examiner indicates that although lida does not teach a composition combining each of these components or capsicum extract in the presently claimed percent range, a skilled artisan would have allegedly still found the presently claimed subject matter obvious in view of lida.

In view of the following, Applicants respectfully traverse this rejection.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ... it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ 1016, 1023 (C.C.P.A 1970). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Applicants submit that a prima facie case of obviousness has not been established because lida does not teach or suggest every element of the claimed subject matter. In addition, Applicants submit that the presently claimed patches are unexpectedly superior over the patches in the cited art.

Independent claim 1 is directed to a warming patch, comprising: a support; and an adhesive layer disposed on at least one surface of said support, the adhesive layer comprising a warming material, l-menthol, and polyethylene glycol as a residual irritation reducing agent, and the amount of said l-menthol and said polyethylene glycol are respectively 0.5-1.5 mass% and 3-25 mass%, based on the total amount of said adhesive layer. Claims 2 and 3 depend from claim 1.

In contrast, lida describes a patch that suppresses skin irritation, which comprises l-menthol, or comprises capsicum extract, or comprises l-menthol and polyethylene glycol. However, Applicants note that lida does not teach or suggest **a patch comprising each of a warming material, l-menthol and propylene glycol**, as presently claimed. Applicants note that the patches in Examples 1-4 and 6-11 of lida contain l-menthol with other ingredients, but not a warming material, e.g., capsicum. While Example 5 of lida describes a patch containing capsicum extract, the patch does not contain l-menthol. In this regard, Applicants submit that lida suggests that l-menthol and capsicum extract are not intended to be used in a single patch. Therefore, Applicants submit that lida does not teach or suggest each and every element of the claimed patch in a single embodiment.

In addition, Applicants respectfully submit that the presently claimed warming

patch has the **unexpected property** of causing reduced residual irritation, due to, for example, the warming material, then previously known patches. In this regard, Applicants respectfully draw the Examiner's attention to paragraph six of the present published application.

As a result of intensive studies intended to achieve the aforesaid object, the Inventors discovered that when l-menthol and polyethylene glycol are blended with the adhesive layer of the warming patch, the warming effect of a warming material such as capsaicin is improved despite the cooling effect of l-menthol, and the pleasant feeling due to the moderate warming effect is more long-lasting due to the polyethylene glycol. More surprisingly, they discovered that although the aforesaid effect was obtained while the patch was in use, **polyethylene glycol functions as a residual irritation-reducing agent which largely reduces the residual irritation due to the warming material such as capsaicin after the patch is peeled off**, and thereby arrived at the present invention. It became clear that the blending of l-menthol and polyethylene glycol with the adhesive layer of the warming patch was also excellent from the viewpoint of ease of manufacturing the adhesive layer. (Emphasis Added).

As described in the present application, residual irritation refers to irritation after peeling a patch off. Residual irritation may be characterized as the prickling feeling which results from elevated body temperature. However, Applicants note that residual irritation within the meaning of the present application is not due to a skin condition such as, for example, erythema.

Applicants note that the skin irritation as described in lida is absolutely different from the residual irritation recited in the present claims. Specifically, the skin irritation in lida refers to **itchiness and skin eruptions** which results from **the suppression of evaporation and dispersion of the moisture** in the ointment. See the English translation of lida, first paragraph of page 3.

In contrast, the residual irritation in the present claims refers to ***residual irritation after peeling the patch off, particularly the prickling feeling by elevating body temperature***. See the present application, for example, at paragraphs [0024] and [0085] to [0088].

Applicants submit that, as shown in Table 1, which shows the superior properties of a patch as claimed over similar patches of different formulations, the presently claimed patch is unexpectedly superior over other patches of different formulations. Applicants submit that the presence of this property is sufficient evidence of nonobviousness.

In this regard, Applicants politely draw the Examiner's attention to MPEP § 716.02(a)(III) which states:

Presence of a property not possessed by the prior art is evidence of nonobviousness. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) (rejection of claims to compound structurally similar to the prior art compound was reversed because claimed compound unexpectedly possessed anti-inflammatory properties not possessed by the prior art compound); *Ex parte Thumm*, 132 USPQ 66 (Bd. App. 1961) (Appellant showed that the claimed range of ethylene diamine was effective for the purpose of producing "regenerated cellulose consisting substantially entirely of skin" whereas the prior art warned "this compound has 'practically no effect.'").

Applicants submit that the present specification provides clear evidence that the claimed patch has superior properties.

Therefore, Applicants submit that *Iida et al.* does not render the presently claimed subject matter obvious within the meaning of 35 USC § 103. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

II. At page 4 of the Official Action, claims 1-5 and 8-10 have been rejected under 35 USC § 103(a) as being obvious over Mori (JP 1981-010888), in view of Weiss (US 3,944,663) and Okamoto (JP 06-256183).

The Examiner asserts that it would have been obvious to select polyethylene glycol, and in particular PEG having a molecular weight of 500-20,000 from the list of polyatomic alcohols taught by Mori to provide a warming patch with less skin irritation. The Examiner further asserts that a skilled artisan would have been motivated to modify Mori in view of the weight ranges taught by Weiss and Okamoto.

In view of the following, Applicants respectfully traverse this rejection.

Again, to establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court recently held in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ... it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ 1016, 1023 (C.C.P.A. 1970). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Independent claim 1 is directed to a warming patch, comprising: a support; and an adhesive layer disposed on at least one surface of said support, the adhesive layer comprising a warming material, l-menthol, and polyethylene glycol as a residual irritation reducing agent, and the amount of said l-menthol and said polyethylene glycol are respectively 0.5-1.5 mass% and 3-25 mass%, based on the total amount of said adhesive layer. Claims 2-5 and 8-10 depend from claim 1.

In contrast, Mori describes a heat stimulating patch with suppressed "skin irritation (rash; in Japanese "かぶれ")." The cause of the "skin irritation" is described as a result of the failure of sweat absorption (lines 9 to 14, page 2, translation of Mori), and the problem is solved by using a water base agent, instead of a conventional oily type. However, unlike the presently claimed subject matter Mori does not teach or suggest the specific combination of elements recited in claim 1. Further, Mori fails to point out the residual irritation of a heat stimulating patch, and therefore does not suggest any resolution of residual irritation reduction.

In addition Applicants note that, Mori describes polyethylene glycol as an example of polyatomic alcohols. Mori further describes that "a polyatomic alcohol retains the moisture performance of the base agent for a long period of time and extends the effects." See, English translation of Mori, lines 2-4 of page 3. Accordingly, Mori suggests that polyatomic alcohols acts as a moisturizing agent. However, Mori does not teach the or suggest that polyethylene glycol may reduce the residual irritation from a heat stimulating patch. In this regard, ***Applicants submit that nowhere does Mori teach or suggest the use of polyethylene glycol for reducing the residual***

irritation from a heat stimulating patch. Accordingly, Mori does not teach or suggest all of the elements of the present claims, as required by *In re Wilson*.

Weiss does not remedy the deficiencies of Mori. Weiss describes a homopolymer of ethylene oxide, namely a homopolymer with a main chain similar to polyethylene glycol, but having a different terminal end and a much higher molecular weight than polyethylene glycol. Weiss suggests that this homopolymer, which is different from polyethylene glycol, may reduce the skin irritation. Skin irritation is described by Weiss as “***reddening or chapping of the affected area or in extreme cases, actual cracking of the skin.***” See Weiss, Col. 1, lines 24-26. However, ***Weiss does not teach or suggest reducing residual irritation***, which as is completely different from the skin irritation described by Weiss. Further Weiss utilizes a homopolymer other than polyethylene glycol. Accordingly, Weiss cannot remedy the deficiencies of Mori.

Okamoto does not remedy the deficiencies of Weiss and Mori. Okamoto describes an antiphlogistic analgesic patch. Okamoto further indicates that polyoxyalkylene glycol is blended as an irritation reducing agent. However, similar to Weiss, the “irritation” according to Okamoto means “erythema.” See the Japanese specification of Okamoto, paragraph [0002]. However, Okamoto does not teach or suggest a patch comprising a warming material at all. Applicants submit that whether taken alone, or in combination, Mori and Weiss and Okamoto do not teach or suggest every element of the presently claimed patch.

In addition, as discussed above, Applicants respectfully submit that the presently claimed warming patch has the ***unexpected property*** of causing reduced residual irritation, due to, for example, the warming material, then previously known patches.

As described in the present application, residual irritation refers to irritation after peeling a patch off. Residual irritation may be characterized as the prickling feeling which results from elevated body temperature. However, Applicants note that residual irritation within the meaning of the present application is not due to a skin condition such as, for example, erythema.

Applicants submit that, as shown in Table 1, which shows the superior properties of a patch as claimed over similar patches of different formulations, the presently claimed patch is unexpectedly superior over other patches of different formulations. Applicants submit that the presence of this property is sufficient evidence of nonobviousness.

In this regard, Applicants politely draw the Examiner's attention to MPEP § 716.02(a)(III) which states:

Presence of a property not possessed by the prior art is evidence of nonobviousness. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) (rejection of claims to compound structurally similar to the prior art compound was reversed because claimed compound unexpectedly possessed anti-inflammatory properties not possessed by the prior art compound); *Ex parte Thumm*, 132 USPQ 66 (Bd. App. 1961) (Appellant showed that the claimed range of ethylene diamine was effective for the purpose of producing "regenerated cellulose consisting substantially entirely of skin" whereas the prior art warned "this compound has 'practically no effect.'").

Applicants submit that the present specification provides clear evidence that the claimed patch has superior properties.

Therefore, Applicants submit that, taken alone or together, none of the cited references teach or suggest every element of the claimed subject matter. In addition, Applicants submit that the claimed patches possess an unexpected superior property. Thus, reconsideration and withdrawal of this rejection is respectfully requested.

III. At page 13 of the Official Action, claims 6 and 7 have been rejected under 35 USC § 103(a) as being unpatentable over Mori in view of Weiss and Okamoto, and in further view of Iida.

The Examiner asserts that it would have been obvious to have selected the triple layer carrier support taught by Iida for use with Mori's patches. The Examiner further asserts that a skilled artisan would have been motivated to modify Mori in view of the weight ranges taught by Weiss and Okamoto.

Both the presently claimed subject matter and each of the references cited in this rejection are discussed in detail above. Applicants respectfully submit that, for the reasons set forth above, the combination of Mori, Weiss, Okamoto and Iida also do not teach or suggest all of the elements of the present subject matter. In addition, as discussed above the presently claimed subject matter possesses unexpectedly superior properties not realized by the patches of the prior art.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

IV. At page 12 of the Official Action, claims 1-10 have been rejected under 35 USC § 112, first paragraph.

The Examiner asserts that the claims do not comply with the written description requirement because, allegedly, the specification does not provide express support for PEG weight range of 10-25%.

Applicants respectfully submit that the amendment to claim 1 renders this rejection moot. Specifically, Applicants submit claim has been amended to recite a PEG range of 3-25%. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

CONCLUSION

In view of the foregoing, Applicants submit that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP

A handwritten signature in black ink, appearing to be 'AS', written over a horizontal line.

Susanne M. Hopkins
Registration No. 33,247
Ari G. Zytcer
Registration No. 57,474
Customer No. 20529

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THE NATH LAW GROUP
112 S. West Street
Alexandria, VA 22314
Tel: (703) 548-6284
Fax: (703) 683-8396